

*Good Morning/Afternoon.*

*We are here to discuss many important issues around controlled substances, with a focus on dispensing and recordkeeping requirements.*

*During this training, we will:*

- *Educate you on the dispensing protocol for controlled substances*
- *Determine a forged/altered prescription*
- *Inform you of the DEA requirements for dispensing practices and recordkeeping requirements*
- *Educate you on the current issues relating to controlled substances recordkeeping*
- *Provide guidance on how pharmacists should inform a patient if they refuse to fill a prescription*
- *Build awareness on current CII trends*
- *Present tools that can be utilized to monitor store dispensing practices of CII's and/or specific drugs of concern*

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## Meeting Objectives

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By the end of this training, you will:

- Understand the pharmacist's responsibilities for controlled substance dispensing under the federal regulations
- Understand the CVS/pharmacy Protocol for Dispensing Controlled Substances
- Comprehend the key factors that will identify a store for the Controlled Substance Monitoring Program
- Identify next steps in root cause analysis for your stores
- Know your role in coaching teams to improve dispensing practices

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*At the end of this training, you will be:*

- *Be aware of the prescription drug abuse epidemic*
- *Understand the pharmacist's responsibilities for controlled substance dispensing under the federal regulations*
- *Understand the CVS/pharmacy Protocol for Dispensing Narcotic Drugs for Pain Treatment*
- *Review requirements and best practices with regard to identifying forged or altered prescriptions*
- *Review recurrent controlled substance recordkeeping issues*

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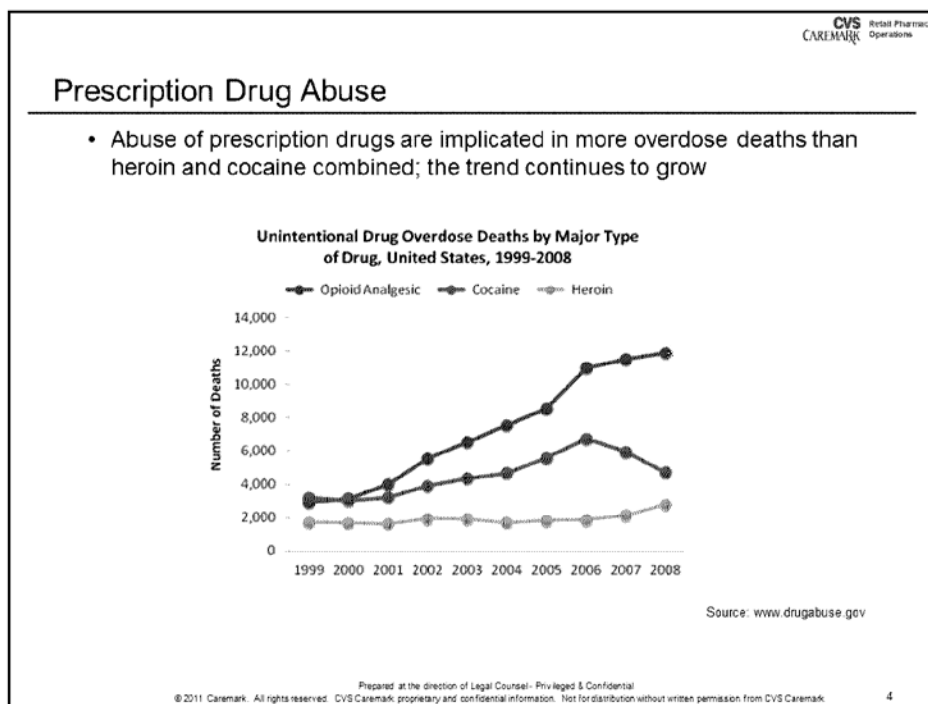
## Prescription Drug Abuse

- Prescription drug abuse is the nation's fastest-growing drug problem
- From 1997-2007, use of prescription opioids increased 402% (per-milligram, per-person)
- The United States utilizes half of all opioids and 80% of all oxycodone produced in the world
- In 2010, 26% of first-time drug abusers began by abusing prescription drugs
  - Perceived as "safer" than street drugs

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*Prescription drug abuse is the nation's fastest-growing drug problem. In 2010, 26% of first-time drug abusers began by abusing prescription drugs since they were perceived as "safer" than street drugs. However, prescription drugs are involved in more overdose deaths than heroin and cocaine combined! From 1997-2007, use of prescription opioids increased 402%.*



*This chart clearly shows how dangerous prescription drug abuse can be.*

## Prescription Drug Abuse in the News

### Oxycodone bust is Pennsylvania's largest-ever prescription drug-related mass arrest, authorities say - UPDATE



By: Karl Broome | The Express-Times  
On March 28, 2015 at 7:20 PM | Updated March 28, 2015 at 8:15 PM

The Pennsylvania Attorney General's Office today announced 51 people face charges in the break-up of competing oxycodone distribution rings run by Monroe County men.

Authorities called it the largest prescription drug-related mass arrest in Pennsylvania history.



### Arrests in drug trafficking ring stretching from Holyoke to Florida expected to reduce oxycodone sold on streets

By CHAD GAIN  
Staff Writer

Published: 4/28/15 at 11:37 AM  
Updated: 4/28/15 at 2:08 PM

Thursday's dismantling of a drug trafficking ring stretching from Holyoke to Orlando, Fla. is expected to cut a significant dent in the supply of oxycodone sold on streets in dozens of communities throughout western New England.

Post

Portland Local News

### Oxycodone smuggling ring leader gets 17 years



by David Krough, KGW.com Staff

Posted on April 28, 2015 at 1:37 PM  
Updated Monday, Apr 28 at 2:08 PM

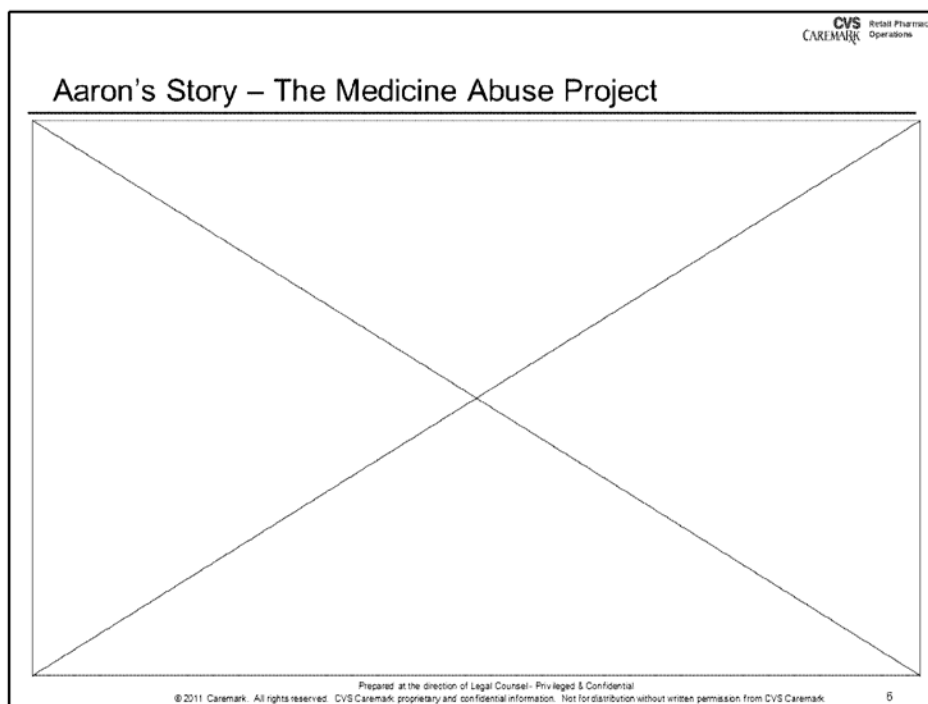
PORTLAND — The leader of a drug-smuggling ring was sentenced to more than 17 years in federal prison by a judge in Portland Monday.

Kingsley Osemwengie, 27, of Las Vegas, Nevada, was sentenced to 210 months in prison as one of 18 people convicted for the largest oxycodone drug operation ever uncovered in the U.S., the Department of Justice said.

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## Corresponding Responsibility

DEA regulations require that a controlled substance prescription “must be issued for a **legitimate medical purpose** by an individual prescriber acting in the usual course of his professional practice.”

Initial responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner

DEA regulations place a “**corresponding responsibility**” on the pharmacist who fills the prescription

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DEA regulations require that a controlled substance prescription be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.

Initial responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner. The corresponding responsibility falls on the pharmacist who fills the prescription.

## Corresponding Responsibility

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A pharmacist must use **reasonably diligent efforts and judgment** to determine if a prescription is issued for a **legitimate medical purpose**.

A pharmacist fails to satisfy their **corresponding responsibility** when they **knew or should have known** that a prescription was not issued for a **legitimate medical purpose**.

Pharmacists must understand that this may be due to a rogue prescriber or due to a patient misrepresenting themselves to a legitimate prescriber. A pharmacist has responsibility in both scenarios to identify if the prescription is for a **legitimate medical purpose**.

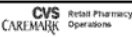
A pharmacist cannot be **willfully blind** to the signals that a prescription was illegitimate.

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A pharmacist must use reasonably diligent efforts and judgment to determine if a prescription is issued for a legitimate medical purpose. A pharmacist fails to satisfy their corresponding responsibility when they knew or should have knows that a prescription was not issued for a legitimate medical purpose. A pharmacist cannot be willfully blind to the signals that a prescription was illegitimate.





## Dispensing Protocol

CVS Caremark has created the Protocol for Dispensing Controlled Substances to aid pharmacists in meeting their corresponding responsibility.

**CVS Caremark**  
**PROTOCOL FOR DISPENSING NARCOTIC DRUGS FOR PAIN TREATMENT**

*Pharmacists must exercise their professional judgment to meet potentially conflicting challenges posed by the therapeutic imperative to optimize outcomes and the regulatory imperative to prevent drug diversion. State and Federal laws and regulations impose a corresponding responsibility on pharmacists to dispense medicine only for legitimate medical purposes and CVS Caremark seeks to ensure that its pharmacists are fulfilling that corresponding duty at all times.*

*CVS Caremark expects and supports decisions by its pharmacists to not fill prescriptions if, in the sound exercise of their professional and clinical judgment they believe or suspect that the prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.*

*Below are some important guidelines for pharmacists:*

1. You should suspend filling all controlled substance prescriptions from practitioners you believe or have reason to doubt are issuing prescriptions for legitimate medical purposes in the course of a valid doctor/patient relationship. Notify your pharmacy supervisor of such action.
2. You should exercise particular caution before filling a prescription:
  - a. if you believe or have reason to doubt that the practitioner has issued the prescription for a legitimate medical purpose in the course of a legitimate doctor/patient relationship, regardless of whether the prescription is otherwise "valid" on its face;
  - b. from practitioners who prescribe the same medication in the same dosage amounts to *most or all* of their patients (e.g., oxycodone 50mg, 180 dosage units) - the use of prescriptions that are preprinted or stamped with the drug type and amount should be cause for concern;
  - c. from practitioners who routinely prescribe the same combination of drugs for pain treatment for *most or all of their patients, particularly where DEA has identified that combination as potentially abused* (e.g., oxycodone, alprazolam and Soma);
  - d. from practitioners who you are aware do not take insurance or whose patients have insurance but always insist on paying cash for their prescriptions;

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*CVS Caremark has created the Protocol for Dispensing Narcotic Drugs for Pain Treatment. This protocol is to be used as an aid to pharmacists in making decisions to meet their corresponding responsibility.*

*Add where they can get the protocol*

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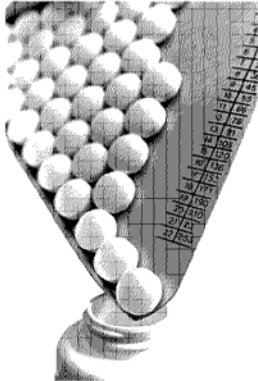
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## Dispensing Protocol

Revised protocol was issued in January 2012

Not limited to oxycodone

Corresponding responsibility applies to all controlled substance prescriptions



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*The protocol was issued in January 2012. It is not limited to just oxycodone; it applies to all narcotic pain drugs. The corresponding responsibility applies to all controlled substance prescriptions.*

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## Dispensing Protocol

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Expectation of pharmacists –

*“CVS Caremark expects and supports decisions by its pharmacist to **not** fill prescriptions if, in the sound exercise of their professional and clinical judgment they believe or suspect that the prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.”*

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*The expectation of pharmacists that is called out in the protocol states that “CVS Caremark expects and supports decisions by its pharmacist to not fill prescriptions if, in the sound exercise of their professional and clinical judgment they believe or suspect that the prescription was not issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.”*

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## Dispensing Protocol

Pharmacist authority to suspend filling for certain prescribers –

*“You should suspend filling all controlled substance prescriptions from practitioners you do not believe or have reason to doubt are issuing prescriptions for legitimate medical purposes in the course of a valid doctor/patient relationship. Notify your pharmacy supervisor of such action.”*

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*Also called out in the protocol is the pharmacists authority to suspend filling for certain prescribers.*

*Pharmacists should suspend filling all controlled substance prescriptions from practitioners you believe or have reason to doubt are issuing prescriptions for legitimate medical purposes in the course of a valid doctor/patient relationship. Notify your pharmacy supervisor of such action.*

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## Dispensing Protocol

A technically valid prescription (date, valid DEA number, signature, etc.) is not enough to satisfy corresponding responsibility

A pharmacist should not fill a prescription if they have reason to doubt that the prescriber has issued the prescription for a legitimate medical purpose in the course of a legitimate doctor/patient relationship, regardless of whether the prescription is otherwise "valid" on its face

Pharmacists must **identify** red flags, **apply** their professional judgment and **decide** to fill or refuse to fill a prescription

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*One thing to note from the protocol is that technically valid prescriptions are not enough to satisfy corresponding responsibility. A pharmacist should not fill a prescription if they have reason to doubt that the practitioner has issued the prescription for a legitimate medical purpose in the course of a legitimate doctor/patient relationship, regardless of whether the prescription is otherwise "valid" on its face.*

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## Apply Professional Judgment

**Pharmacists should contact the prescriber to verify:**

- Any concerns about type and quantity of medication (i.e., 30mg oxycodone prescription for any high quantity > 180 tablets)
- If prescription appears to be duplicative therapy, refill too soon, or if patient has similar scripts from multiple prescribers
- If they have no relationship with the patient/prescriber (contact prescriber to verify diagnosis/therapy, etc.)

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*If there is ever a doubt with the validity of a prescription, pharmacists should contact the prescriber to verify. The pharmacist should contact the prescriber with any concerns about the type and quantity of medication, if the prescription appears to be duplicative therapy, refill too soon or if the patient has similar scripts from multiple practitioners. They should also contact the prescriber if they have no relationship with the patient or the prescriber to verify the diagnosis code, etc.*

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## Apply Professional Judgment

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**Document the verification**

- Verification alone does not render a prescription legitimate
- The prescriber can be the problem
- The patient could be the concern


Even if a prescriber verifies a prescription, a pharmacist should not fill that prescription if they believe or suspect that it was not written for a legitimate medical purpose.

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*If the pharmacist contacts a prescriber because he or she has no relationship with the patient or prescriber, the verification should be documented. Verification alone does not render a prescription legitimate, the prescriber can be the problem.*

*Remember, even if a prescriber verifies a prescription, the pharmacist should not fill the prescription if they believe or suspect that it was not written for a legitimate medical purpose.*



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## Dispensing Protocol

Pharmacists have the authority to decline to fill any prescription where, in the exercise of their professional and clinical judgment, they believe or suspect that it was not issued for a legitimate medical purpose by a prescriber acting in the usual course of professional practice.

If a pharmacist has exercised his or her professional judgment and has determined that a controlled substance prescription was written for a legitimate medical purpose (and if the prescription is otherwise valid and in compliance with federal and state requirements), then the pharmacist can properly dispense the prescription.

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*Remember, pharmacists have the authority to decline to fill any prescription where, in the exercise of their professional and clinical judgment, they believe or suspect that it was not issued for a legitimate medical purpose by a prescriber acting in the usual course of professional practice.*

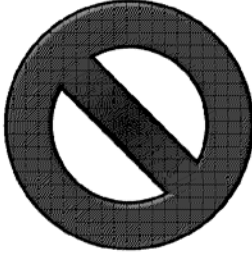


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**Decide – To Fill or To Refuse to Fill**

**Different scenarios may produce different conversations. A straightforward approach is always a best practice. An example is: “After careful clinical evaluation, I am uncomfortable filling this prescription because of <insert red flags>. We cannot fill this prescription here or at any other CVS/pharmacy.”**




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*Under no circumstances should the pharmacist utilize some other “reason” why they cannot fill the prescription or refer a patient they have refused to fill their narcotic prescription for to another pharmacy or even another pharmacist on duty.*

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## Overriding Message

**CVS/pharmacy pharmacists must use their professional judgment with regard to every controlled substance prescription.**

**CVS/pharmacy management will support and back up any pharmacist who exercises his or her professional judgment to fill a legitimate controlled substance prescription or to refuse to fill a prescription that they believe or suspect is not written for a legitimate medical purpose.**

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## DEA Visits

### **If DEA visits a pharmacy:**

- Pharmacist on duty should immediately notify Pharmacy Supervisor
- Provide requested documents in accordance with CVS policies
- Be alert to issues of particular interest/focus of DEA attention
- After visit is concluded, Regulatory Tracker report must be completed
- Immediately after visit, Pharmacist should make notes regarding what DEA asked about, what documents they reviewed, any unfinished business/open questions, etc.
- This information should be forwarded to Pharmacy Supervisor and included in Regulatory Tracker report
- If a letter of admonition/other communication or citation from DEA is received, PIC must notify Pharmacy Supervisor immediately and submit a copy of the document to Regulatory Compliance

## Controlled Substance Dispensing Program Overview

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### **Objective:**

- To assist field managers in proactively identifying stores which exhibit a concerning pattern of dispensing or high rates of growth for controlled substances
- Upon identification, field leadership performs a store level review to diagnose and remediate areas of concern

### **Description**

- An algorithm has been created to monitor store dispensing activity across multiple dimensions and identify the presence of red flags
- This algorithm is run quarterly to identify stores of concern

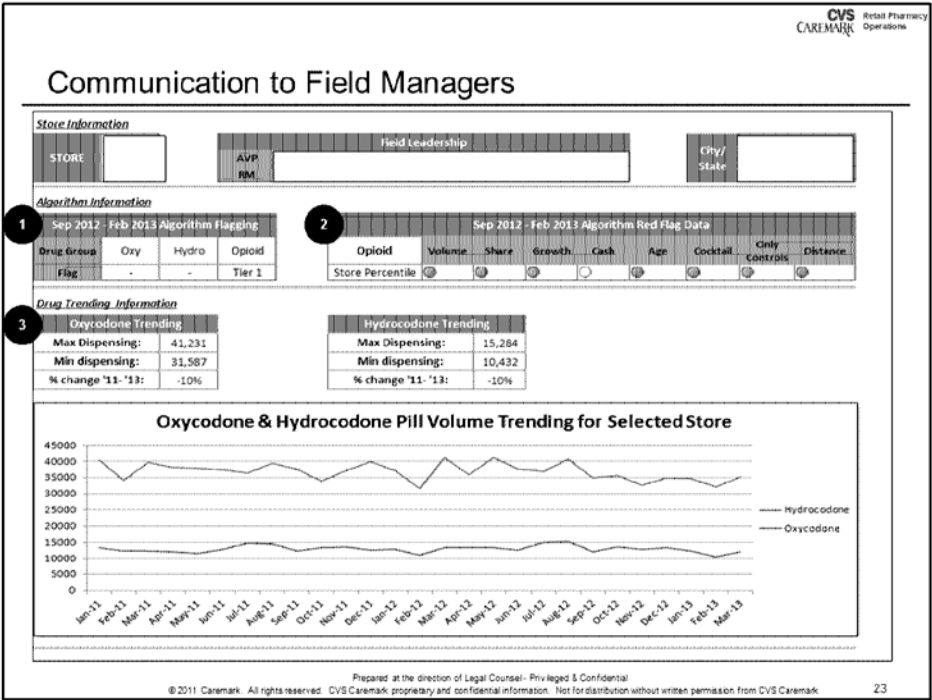
## Controlled Substance Dispensing Program Overview

- The most concerning stores are identified and automatically enter the Controlled Substance Dispensing Program (CSDP), which initiates a targeted review:
  - Field teams are educated on red flags, root cause analysis and coaching
  - RLPM and Pharmacy Supervisor partner to perform a store visit
    - RLPM performs a targeted Controlled Substance Audit
    - Pharmacy Supervisor reviews current filling and through open ended questions works to identify root cause of red flags
    - Pharmacy Supervisor documents red flag findings in Archer
    - Pharmacy Supervisor provides coaching to assist Team Leader in laying out the plan for success and obtains signatures of all pharmacists on CSDP sign-off sheet
  - An Accountability Review Board reviews findings from this visit to determine if any further actions are necessary
- Stores are reviewed on subsequent runs of the algorithm
  - Stores are have an additional cycle to improve their dispensing patterns
  - Further accountability is advised for stores that do not improve their performance

## Parameters for Use of Reporting Information

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- This analysis and subsequent communication is privileged and confidential
- It is being provided to you as the leader of the team. It's purpose is to give you directional information to assist you in identifying root cause behavior and developing an appropriate plan of action
- At no time is this information to be shared or distributed outside your immediate field leadership team (Pharmacy Supervisor, District Manager, Regional Loss Prevention Manager, Region Manager, Human Resources Business Partner and Area Vice President)
- To do so, would constitute a gross violation of CVS policy and could result into consequences up to and including termination









Likely appendix slide









### (3) Oxycodone & Hydrocodone Trending Information

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- **Review trending information to identify areas of concern (growth).**
- **Overlay events that may have occurred to provide color**
  - File Buy
  - Competitor moved or closed
  - Store relocated to a better location/ added drive-thru
- **Use information to support targeted questions around volume and growth**

## Next Steps

**You will partner with your RLPM to perform a Controlled Substance Store Visit in each identified store. This visit is recommended to occur on a flex day or during one of your follow up visits in observance of the SOS cycle.**

### **Identify gaps in knowledge or process:**

- Controlled Substance Audit (Completed by RLPM)
  - Coordinate with your RLPM during the visit to provide insight from your knowledge of the store to add clarity to the findings of the LP audit s/he will be conducting.
- Investigate the red flags at store level that are identified as outliers in the store to gain an understanding of the source for the flagging.
  - Review 30-50 CII hard copies for evidence of the flagged element
  - Ask pharmacists to walk you through their process on handling prescriptions with these elements present.
  - If pharmacist resolved red flags, review to ensure documentation of resolution is adequate
  - Document your findings in Archer

## Notification email to address red flags

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Hello,

One or more stores in your district have been entered into the Controlled Substance Dispensing Program. Entering stores are identified as outliers for controlled substance dispensing of a high risk drug. As a result, specific store level red flags require your action and investigation. Please click the link below for a report identifying the red flags for which further information is required.

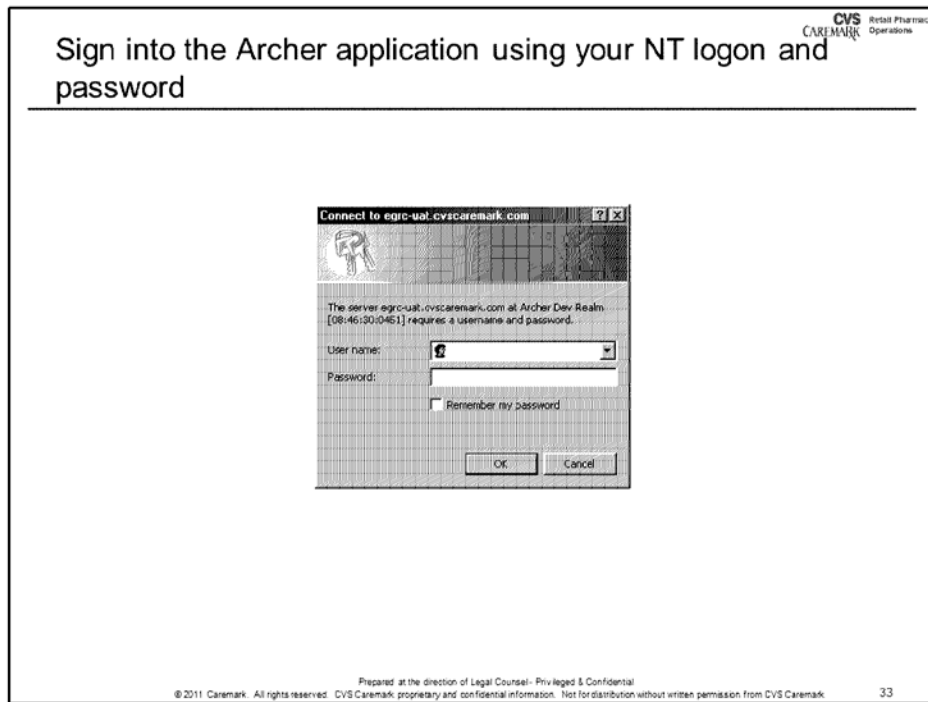
<https://egrc-uat.cvscaremark.com/archer/default.aspx?requestUrl=..%2fSearchContent%2fSearch.aspx%3fView%3dReport%26reportid%3d7405%26moduleid%3d476>

As the Pharmacy Supervisor you must review 30-50 controlled substance prescriptions for medications within the same class as the identified drug of concern and document your findings for each listed red flag on the provided electronic worksheet. This action must be completed as part of your CS Visit conducted in partnership with your RLPD within 30 days of receipt of this email.

Regards,

The Professional Practice Standards Team





Once logged in, you will be brought to a page specific to identified red flags in your district which require further research.

# RSA Archer eGRC

*Enterprise Governance, Risk and Compliance*

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**Home**
Vendor Assessment
Drug Loss Program
PIC POA Program
CS Monitoring
PEM HIPAA
More ▾

Submit Issue, Request, or Question | View IRQ Tickets

## Red Flags

New  
 Modify  
 Save  
 Reports

<<    <    1 to 5 (of 5)    >    >>

Export  
 Print  
 Email

**My Open Red Flags - Rx Sup**
[ Options ▾ ]

Drag a column name here to group the items by the values within that column.					
Red Flag ID	Red Flag	Drug of Concern ▲	Store Number	Due Date	Privileged and Confidential Flag
3651000	Volume	<u>Anytyme Drug</u>	8	6/13/2013	Privileged and Confidential
3651058	Volume	<u>Big Time Drug</u>	8	6/13/2013	Privileged and Confidential
3651053	Age	<u>Finstones Chewables</u>	25	6/14/2013	Privileged and Confidential
3651059	Volume	<u>Small Time Drug</u>	8	6/13/2013	Privileged and Confidential
3624189	Distance	<u>Some Drug</u>	6757	6/17/2013	Privileged and Confidential

Page 1 of 1 (5 records)

Select edit to record your Root Cause Findings and any other additional pertinent notes

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Red Flags: Anytime Drug

First Published: 6/12/2013 6:12 PM Luehning, Shawna Last Updated: 6/12/2013 6:12 PM Luehning, Shawna

Record 1 of 5

Export Print Em

Privileged and Confidential

This record and its contents are Privileged and Confidential

General Information

Red Flag ID: 3651000

Store Number: 8

Red Flag: Volume

Root Cause Findings:

Additional Notes:

Response Status: Drafting

Due Date: 6/13/2013

Drug of Concern: Anytime Drug

Selecting edit will open the record to allow you to record your findings

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Enter your detailed findings then change the status to Complete and Save

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### Red Flags: Anytime Drug

Record 1 of 5

**General Information**

Red Flag ID:	3651060		
Store Number:	8	Due Date:	6/13/2013
* Red Flag:	Volume	* Drug of Concern:	Anytime Drug
* Root Cause Findings:	Test reason 1 Test reason 2		
Additional Notes:	Additional findings may be added here		
* Response Status:	<input type="radio"/> Drafting <input checked="" type="radio"/> Complete		

**The red flag will remain as an open opportunity until you select the Complete status and hit Save**

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Once Save is selected, the record will be removed from your opportunity dashboard

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**My Open Red Flags - Rx Sup** | Options ▾ |

Drag a column name here to group the items by the values within that column.

Red Flag ID	Red Flag	Drug of Concern ▲	Store Number	Due Date	Privileged and Confidential Flag
3651060	Volume	<u>Anytime Drug</u>	8	6/13/2013	Privileged and Confidential
3651068	Volume	<u>Big Time Drug</u>	8	6/13/2013	Privileged and Confidential
3651053	Age	<u>Filinstones Chewables</u>	25	6/14/2013	Privileged and Confidential
3651059	Volume	<u>Small Time Drug</u>	8	6/13/2013	Privileged and Confidential
3624189	Distance	<u>Some Drug</u>	6757	6/17/2013	Privileged and Confidential

Page 1 of 1 (5 records)

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**My Open Red Flags - Rx Sup** | Options ▾ |

Drag a column name here to group the items by the values within that column.

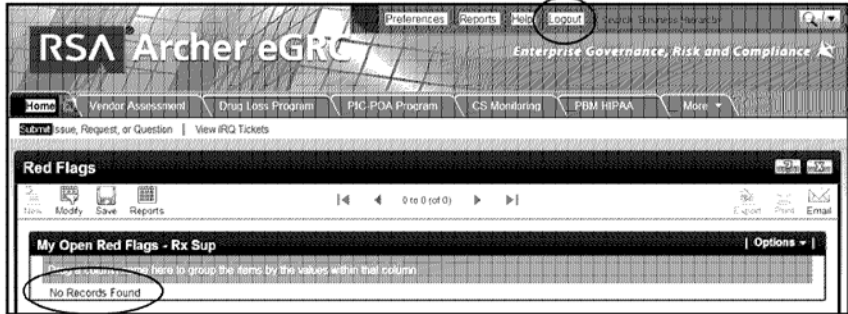
Red Flag ID	Red Flag	Drug of Concern ▲	Store Number	Due Date	Privileged and Confidential Flag
3651050	Volume	<u>Big Time Drug</u>	8	6/13/2013	Privileged and Confidential
3651053	Age	<u>Filinstones Chewables</u>	25	6/14/2013	Privileged and Confidential
3651059	Volume	<u>Small Time Drug</u>	8	6/13/2013	Privileged and Confidential
3624189	Distance	<u>Some Drug</u>	6757	6/17/2013	Privileged and Confidential

Page 1 of 1 (4 records)

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Record your findings in each open red flag opportunity, until no records remain on your dashboard



Once all red flags have been address, you may log out of the application  
Remember you have 30 days from receipt of the email to address all red flags

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## Next Steps

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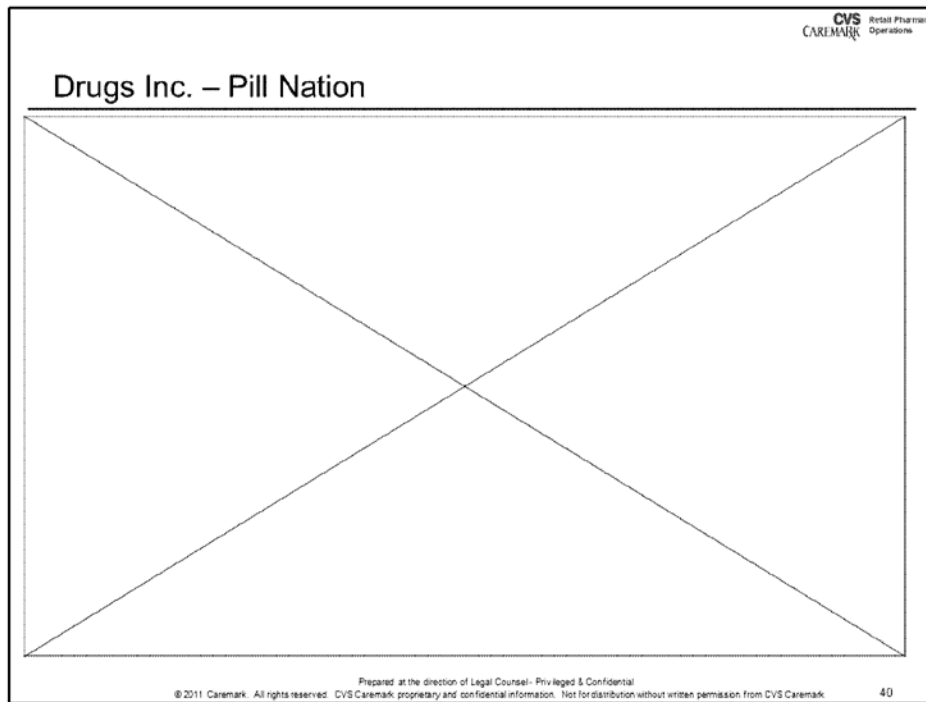
### **Educational Component**

- As part of that Controlled Substance store visit you will be required to:
  - Review with each Pharmacist the company Controlled Substance Dispensing Guidelines and reinforce Corresponding Responsibility
  - Leverage the talking points provided to guide your discussion

**Return your required documents within 30 days (no later than July 17, 2013) to michelle.travassos@cvscaremark.com to include:**

- Statement of understanding and commitment


**The RLPM will return their Controlled Substance Audit to the LP department (John Robinson).**





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Questions?



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*Are there any questions?*